Introduction to Biological and Small Molecule Drug Research and Development: Chapter 5. Similarities and differences in the discovery and use of biopharmaceuticals and small-molecule chemotherapeutics

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Biotechnology has given rise to a broad range of biotherapies or biologics, including biomolecular drugs, vaccines, cell or gene therapies. This chapter focuses on biomolecular drugs, namely monoclonal antibodies (Mabs), cytokines, tissue growth factors and therapeutic proteins. Prior to the US approval of recombinant human insulin in 1982, biomolecular drugs were extracted from natural sources. The tools of molecular biology have dramatically increased the discovery and development of new biopharmaceuticals. The most obvious difference between small-molecule drugs (SMDs) and biomolecular drugs is size, like the difference in weight between a bicycle and a business jet. SMDs and biomolecular drugs are compared in this chapter by structure, molecular weight, preparation, physicochemical properties, and route of administration, as well as distribution, metabolism, serum half-life, dosing regimen, species reactivity, antigenicity & hypersensitivity, clearance mechanisms, drug–drug interactions, and pharmacology. This chapter reviews the differences and similarities in the various stages of drug discovery and development, with respect to cost, probability of success and cycle time. The clinical metrics of overall clinical success rate, stage-related success rate, and clinical cycle time are examined for SMDs and biomolecular drugs. The hybrid class of peptide drugs tends to be equated with biologics, due to their amino acid content and because oral activity is rare. But peptides truly bridge the gap between small molecules and biologics, in terms of physical properties, range of therapy areas and means of production. This chapter summarizes the similarities and differences of peptide drugs with SMDs and biomolecular drugs. The manner in which these agents compare as products with respect to manufacturing and pricing are considered. Two case studies are presented—the antagonists where small-molecule, peptide and Mab agents have competed in the market, and Her2 inhibitors where small-molecule and Mab agents may ultimately synergize as a combination product. Biomolecular drugs have levelled the playing field. All the “big Pharma” companies now have the capacity to develop both types of drugs. Conversely the larger biotech companies are developing the capacity for small-molecule synthesis. Now, with many blockbuster biologics nearing patent expiration, biosimilars are on the way. It's no longer a question of “choose which type”—one will need to know how to discover and develop either type of drug.

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